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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOWMEDICA OSTEONICS CORP., Plaintiff, v. WRIGHT MEDICAL TECHNOLOGY, INC., Defendant.	Civil Action No.: 00-cv-1167 (JLL) **OPINION AND ORDER**

LINARES, District Judge.

INTRODUCTION

This matter comes before the Court by application for claim construction by Plaintiff Howmedica Osteonics Corp. (hereinafter "Plaintiff" or "Howmedica") and Defendant Wright Medical Technology, Inc. (hereinafter "Defendant" or "Wright Medical"). This lawsuit concerns United States Patent No. 5,824,100 ("the '100 patent"), entitled "Knee Prosthesis With Increased Balance and reduced Bearing Stress." Howmedica brings this action against Wright Medical for willful patent infringement. Jurisdiction and venue are proper pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391(b), and 1400(b). This Opinion addresses the proper construction with respect to portions of Claim 15 of the '100 patent.

FACTUAL AND PROCEDURAL BACKGROUND

Both Howmedica and Wright Medical are engaged in the business of "developing, manufacturing and marketing" orthopedic implants for use in the reconstruction of various joints of the human body. (Compl. ¶¶ 5-6). Howmedica owns the '100 patent, which was issued by the United States Patent and Trademark Office (hereinafter "PTO") in October 1998.[1] The '100 patent is directed to an artificial knee implant for restructuring the knee joint.[2] Howmedica alleges that Wright Medical has infringed the '100 patent by the manufacture, use, offer for sale, and/or sale of its knee implant product sold in connection with Wright Medical's ADVANCE® Total Knee System. (Compl. ¶11).

At issue in this action are certain portions of independent Claim 15 of the '100 patent. Claim 15 reads as follows:

> In a knee prosthesis for replacing the natural knee, the knee prosthesis having a femoral component and a tibial component, the tibial component including a bearing member and the femoral component including at least one condylar element for confronting and engaging the bearing member to accomplish articulation of the knee prosthesis throughout the range of flexion, including a primary range of flexion between a hyperextended position and a flexed position, the engagement between the condylar element of the femoral component and the bearing member of the tibial component ordinarily taking place at a contact area along articular surface areas of the condylar element and the bearing member, the improvement comprising:
>
> anterior-posterior surface profile contours along condylar element and the bearing member, the anterior-posterior

[1]The named inventors are Mark A. Koster and Marc G. Weissman.

[2]This patent is also variously referred to as the "Scorpio® Knee patent," "epicondylar axis patent, "the epi axis patent," or the "epi patent."

> surface profile contour along the condylar element having an essentially constant anterior-posterior articular radius throughout the articular surface area of the condylar element which contacts the bearing member during articulation throughout the primary range of flexion, the anterior-posterior articular radius having an origin lying generally along a line extending laterally between the medial and lateral collateral ligament attachment points on the femur of the natural knee.

('100 patent, Cl. 15).

On March 10, 2000, Howmedica filed the instant action against Wright Medical for alleged patent infringement of the '100 patent. Thereafter, the parties fully briefed the issue of the proper interpretation of those portions of Claim 15 at issue.[3] Accordingly, on June 9, 2004, this Court conducted a Markman hearing.[4] Additionally, the parties cross-moved for summary judgment on Wright Medical's Fifth Affirmative Defense. The affirmative defense provides that "[t]his action is barred by virtue of a Settlement and License Agreement Among Wright Medical Technology Inc., Howmedica Osteonics Corp., Stryker Corporation and Stryker Technologies Corporation effective as of December 16, 1999." (Amend. Ans. ¶ 20). By Opinion and Order dated March 17, 2005, this Court denied the cross-motions for summary judgment.

Presently, this Court must determine the correct construction of various terms as used in Claim 15 of the '100 patent.

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[3]By joint letter dated June 7, 2004, the parties advised this Court that they agreed to the construction of seventeen claim terms.

[4]It should be noted that supplemental post-Markman materials were submitted by the parties up through July 22, 2005.

DISCUSSION

A. Law of Claim Construction

Determining patent infringement requires a two-step analysis. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1999). First, the court must determine, as a matter of law, the correct scope and meaning of any disputed claim terms. Id.; see also Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996); Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1562 (Fed. Cir. 1990) (recognizing that the patent claim interpretation process requires review of the scope of the patent claim). Second, the court compares the properly construed claims to the accused device (or method) and determines whether the accused device contains all of the limitations of the claimed invention. Johnson Worldwide, 175 F.3d at 988.

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). In construing the terms of a patent, a court should look first to the language of the claim itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The terms in the claim "are generally given their ordinary and customary meaning." Id. at 1582. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313. A court "must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005). The court should look to "those sources available to the public that show

what a person of skill in the art would have understood disputed claim language to mean." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004).

To this end, the court should first examine the intrinsic record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Vitronics, 90 F.3d at 1582 (citing Markman, 52 F.3d at 979). The specification, for example, "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 158. Indeed, the Federal Circuit explains that the specification is "'usually ... dispositive ... [and] the single best guide the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Moreover, the Federal Circuit confirms that it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Phillips, 415 F.3d at 1317. Additionally, a district court should also consult the patent's prosecution history. However, the Federal Circuit warns that since the prosecution history represents "an ongoing negotiation between the PTO and the applicant, rather than the final product of the negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id. Finally, the Federal Circuit confirms that the district court is authorized to rely on extrinsic evidence such as dictionaries and treatises. However, the court indicates that this evidence is generally less reliable than the patent and prosecution history, noting that although "extrinsic evidence may be useful to the court, [] it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Phillips, 415 F.3d at 1319.

With this framework in mind, the Court now turns to the disputed claim language.

B. The Disputed Claim Terms

In view of the June 7 letter jointly submitted by the parties, it appears that the remaining disputed language of the '100 patent consists of the following: (1) "at least one condylar element;" (2) "primary range of flexion;" and (3) "lying generally along a line extending laterally between the medial and lateral collateral ligament attachment points on the femur of the natural knee."

1. "at least one condylar element"

The parties disagree as to the proper interpretation of the term "femoral component including at least one condylar element." They do not contest that "condylar element" means "condyle" and "at least one" means "one or more." Rather, the dispute centers around the remainder of the claim, which sets forth the specific requirements on each condylar element. Specifically, Howmedica contends that the clause "at least one" means that in a bi-condylar knee, only one of the condyles needs to meet the requirements of the claim. Wright Medical counters that in bi-condylar knees, both condyles must meet those requirements.

Initially, Wright Medical asserts that the claims of the '100 patent must be limited to the disclosed embodiment. This Court agrees that the specification discloses only one embodiment, namely, a bi-condylar femoral component with both condyles described as meeting all the requirements of the claim. The specification recites:

> As best seen in Fig. 3, anterior-posterior profile contour 74 of knee prosthesis 20 includes an essentially constant anterior-posterior articular radius 90 throughout a region 92 of each condylar element 52.

('100 patent col. 3, lines 52-55). The Federal Circuit, however, has rejected the proposition that the patent must be construed as limited to that embodiment. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (citing authorities). As the court has noted:

> [T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.

Id. (internal citations and quotations omitted); see also Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1372 (Fed. Cir. 2003) ("[M]erely because the specification only describes one embodiment is not a sufficient reason to limit the claims to that embodiment."); SRI Intern. v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) ("That a specification describes only one embodiment does not require that each claim be limited to that one embodiment."). Therefore, the Court now turns to the specification.

In further support of its proposed construction, Wright Medical points to the language of the specification describing certain "objects and advantages" allegedly met by the implant. ('100 patent col. 1, lines 38-62). One such advantage claimed by the '100 patent is "increased areas of contact between the condylar elements of the femoral component of the knee prosthesis and the bearing member of the tibial component for lowered stress in the material of the bearing member." ('100 patent col. 1, lines 48-53). The fact that the inventors use the plural form ("condylar elements") when describing their invention provides support for Wright Medical's proposed construction. In addition, a second advantage asserted is that the invention "attains a better balance of the tension in the collateral ligaments of the knee during articulation of the

knee prosthesis." ('100 patent col. 1, lines 53-55). However, as Wright Medical's expert, Dr. Bradley, observed:

> To have a better "balance" of both collateral ligaments you would need the cause of that balance to be in effect of both condyles of a bicondylar femoral component; this would not occur if one condylar element had some arbitrary non-constant radius geometry....

(Johnston Decl. Ex. 21 at 12). Other advantages claimed in the patent are "a higher degree of conformity between the condylar elements and the bearing member for reduced stresses during normal activity...." ('100 patent col. 1, lines 55-58). Once again, the condylar elements are identified in the plural tense. In view of the foregoing, it appears to this Court that the patent is clearly concerned with better balance in both collateral ligaments, not just one.

Additionally, Wright Medical points to the testimony of one of the inventors to establish that both condyles of a bi-condylar femoral component must meet the requirements of the claim. Clearly, a Court can consider an inventor's testimony "explain[ing] the invention and what was intended to be conveyed by the specification and covered by the claims." Voice Technologies Group, Inc. v. VMC Sys., Inc., 164 F.3d 605, 615 (Fed. Cir. 1999); see also Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1580 (Fed. Cir. 1996) (noting that inventor's can be treated as "cumulative to the other evidence, and as enlarging our understanding of the technology and the usage of the disputed terms."). As stated by the Federal Circuit,

> This court in Markman did not hold that the inventor can not explain the technology and what was invented and claimed; the Federal Circuit held only that the inventor can not by later testimony change the invention and the claims from their meaning at the time the patent was drafted and granted.

Voice Technologies, 164 F.3d at 615. Dr. Kester, one of the inventors, testified that he intended for both condyles to be identical. He testified as follows:

> Q: Okay. And for the total knee which had two condylar elements, was it your intention that both condylar elements would meet the requirements of having the constant anterior-posterior radius throughout the primary range of flexion.
> A: That radius being centered on the footprint of the collateral ligament attachment site to the femur.
> Q: As well?
> A: Yes.

(Johnston Decl. Ex.20 at 144). Dr. Kester also emphasized the importance of having the same radii on both condylar elements, noting that "differing radial values on the medial and lateral [condlyes] would have certain implications with regard to the bone cuts on the tibia as well as the polyethylene thickness on the tibia, both of which are critical and not to be taken lightly." (Id. at 227).

All of the foregoing clearly supports the proposed construction of the term "femoral component including at least one condylar element" to mean that in bi-condylar knees, both condyles must meet those requirements. As such, this construction will be adopted by this Court.[5]

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[5]During the Markman hearing, Howmedica argued that given that Claim 1 was narrower than Claim 15, the term "femoral component including at least one condylar element" could be given a different meaning in Claim 1 than in Claim 15. However, "[t]he fact that we must look to other claims using the same term when interpreting a term in an asserted claim mandates that the term be interpreted consistently in all claims." Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995). Hence, this argument fails given this Court's determination on construction.

2. "primary range of flexion"

Both parties agree that "primary range of flexion" does not have an ordinary and customary meaning to one possessing ordinary skill in the art. The specification provides, in relevant part:

> The regions 92 include those portions of the articular surfaces 26 of the condylar elements 54 which contact the bearing member 64 during articulation throughout a portion of the full range of flexion of the knee prosthesis 20, between hyperextesion and full flexion, the portion of the full range being the primary range of flexion between a hyperextended position and a flexed position, defining the portion of the full range of flexion within which most normal activities occur. **Thus, the primary range of flexion, as depicted in FIGS. 4 thorough 7, is from a hyperextended position of about -15°, as seen in FIG. 4, to a flexed position of about 75°,** as seen in FIG. 7.

('100 patent col. 3, lines 55-67) (emphasis supplied). Wright Medical argues that in light of the specification, this phrase should be construed in accordance with the range disclosed in the patent; namely, from -15° of hyperextension to +75° of flexion. Howmedica counters that Wright Medical's interpretation violates the principle of "claim differentiation" because the meaning of "primary range of flexion" asserted in Claim 15 is exactly what is set forth in Claim 18. The doctrine of claim differentiation gives rise to the presumption that a limitation set forth in a dependant claim is not present in an independent claim. Phillips, 415 F.3d at 1314-15. Claim 18 recites:

> The improvement of claim 15 wherein the hyperextended position is at about -15° in the range of flexion, and the flexed position is at about 75° in the range of flexion.

('100 patent col. 8, lines 8-10). Howmedica maintains that if this Court were to accept Wright Medical's interpretation, the meaning of "primary range of flexion" in independent Claim 15 is

the same as what is set forth in dependant Claim 18. On the issue of claim differentiation, the Federal Circuit states:

> There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.

Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987). "Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement." Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054-55 (quoting D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574 (Fed. Cir. 1985)). Because Claim 18 includes a specific range, this Court agrees that a presumption arises that Claim 15 does not include that limitation.

Nonetheless, this Court concludes that this presumption is overcome by the narrow definition given to "primary range of flexion" by the patentees in the specification. Given that the specification clearly states that "primary range of flexion" is limited to a particular range of -15° to +75°, the Court finds that the patentees acted as their own lexicographers and limited the meaning of "primary range of flexion." See e.g., Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1339-40 (Fed. Cir. 2004) (finding that the inventors acted as their own lexicographers); see also Energy Absorption Sys., Inc. v. Roadway Safety Svcs., Inc., 1997 WL 368379, *3 (Fed. Cir. Jul. 3, 1997) ("[A] patentee may be his own lexicographer and where the patentee gives a term a certain meaning in the written description, that meaning will apply when interpreting the term as used in the claim.") (citation omitted). To be sure, "the doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the

specification and the prosecution history and any relevant extrinsic evidence." Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed. Cir. 1998). Hence, "primary range of flexion" is construed to mean -15° of hyperextension to +75° of flexion.[6]

3. "lying generally along a line extending laterally between the medial and lateral collateral ligament attachment points on the femur of the natural knee" (i.e., the "epicondylar" or "transepicondylar" axis)

Howmedica asserts that "lying generally along a line extending laterally between the medial and lateral collateral ligament attachment points on the femur of the natural knee" should be construed to mean that "the origin of the essentially constant articular radius of the femoral component will lie on or about the epicondylar axis, which axis extends between the medial epicondyle and the lateral epicondyle and passes through the medial and lateral collateral ligament attachment points on each side of the natural knee." (Pl.'s Br. at 23). Wright Medical responds that this phrase is indefinite because it does not reasonably apprise someone skilled in the art as to which line is claimed. As mandated by the definiteness requirement set forth in 35 U.S.C. § 112, ¶ 2, a specification shall include claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." The definiteness requirement "focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the [scope of the] patentee's right to exclude." Honeywell Int'l, Inc. v. Int'l Trade Comm., 341 F.3d 1332, 1338 (Fed. Cir. 2003)

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[6]During the Markman hearing, Howmedica also acknowledged that the patent Examiner observed that "primary range of flexion" was defined in the specification as meaning from -15° of hyperextension to +75° of flexion. (Hr'g Tr. at 128). Howmedica now argues that this definition should not apply because the Examiner did not require Howmedica to expressly include same into the claim. However, Howmedica cites to no authority for the proposition that every definition claim that is recited in the specification must also be expressly set forth in the claim.

(quoting S3 Inc. v. nVIDIA Corp., 259 F.3d 1364, 1371-72 (Fed. Cir. 2001)). Defendants must sustain their burden of proving by clear and convincing evidence that claims are invalid as indefinite. W.R. Grace & Co.-Conn. v. Intercat, Inc., 7 F. Supp. 2d 425, 466 (D. Del. 1997), aff'd, 155 F.3d 572 (Fed. Cir. 1998).

Wright Medical argues that Howmedica's use of a word of degree such as "generally," renders the claim indefinite. The mere fact that "some claim language may not be precise, however, does not automatically render a claim invalid. When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree." Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc., 731 F.2d 818, 826 (Fed. Cir. 1984). Here, the written description of the specification does reference the term "generally along," providing:

> By locating the center 94 of the essential constant anterior-posterior articular radius 90 generally along the line 96, a better balance is attained in the tension in the collateral ligaments 30 and 32 during articulation of the knee prosthesis 20, resulting in better performance.

('100 patent col. 4, lines 10-15). Therefore, this Court does not find that the claim is rendered indefinite solely because of the use of the term "generally." Rather, the determination of whether a claim is definite requires an analysis of "whether one skilled in the art would understand the bounds of the claim when read in light of the specification.... If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." Miles Lab., Inc. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993); see also Hybridtech v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385 (Fed. Cir. 1986)

(finding that claims need only "reasonably apprise those skilled in the art" as to their scope to meet the definiteness requirement), cert. denied, 480 U.S. 947 (1987).

Turning to the facts at bar, Wright Medical argues that epicondylar axis does not have a clear meaning to one of ordinary skill in the art because it is difficult to ascertain the epiconylar or transepicondylar axis for purposes of infringement. In support, Wright Medical's expert, Dr. Bradley, testified that the epicondylar axis was hard to identify because the epiconyles can be up to an inch in diameter. (Hr'g Tr. 65). However, under the facts of the case, the purported difficulty in ascertain the epiconylar or transepicondylar axis is not sufficient to warrant a finding of indefiniteness and overcome the presumption of patent validity. As the Federal Circuit has noted, "a claim is not indefinite merely because it poses a difficult issue of claim construction; if the claim is subject to construction, i.e., it is not insolubly ambiguous, it is not invalid for indefiniteness. Bancorp Svcs., L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1371 (Fed. Cir. 2004) (citing Honeywell, 341 F.3d at 1338-39). To be sure, claims need not "be plain on their face in order to avoid condemnation for indefiniteness; rather, what [this court has] asked is that the claims be amenable to construction, however difficult that task may be." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Moreover, "[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." Id.

This Court finds that the written description of the specification is sufficient to inform one skilled in the art of the bounds of the invention. This conclusion is supported by the fact that Wright Medical's own literature uses the term transepicondylar axis. For instance, a Wright

Medical brochure for the ADVANCE® Total Knee System provides: "In the normal knee, kinematic studies show that the tibia rotates in flexion about the transepicondylar axis." (Kochanski Decl. Ex.A at 2). Further, Wright Medical's surgical technique guide even referenced the epicondylar axis, providing: "Note: In cases with significant wear or severe deformation of the posterior condlyes, the 0° guide can be used with a tommy pin to set rotation manually using the A-P or epiconylar axis...." (Pl.'s Ex.1). Given the foregoing, the Court is persuaded that Claim 15 clearly delineates to a skilled artisan the bounds of the invention. As such, Wright Medical has not met its burden to demonstrate clearly and convincingly that the '100 patent is indefinite as a matter of law simply because it is difficult to ascertain the epiconylar or transepicondylar axis for purposes of infringement. Hence, Wright Medical fails to establish to this Court that the phrase "lying generally along" is invalid for indefiniteness.

CONCLUSION

ACCORDINGLY, having considered the submissions of the parties and following oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED and DECREED that the Court construes the disputed claim language of the United States Patent No. 5,824,100 as follows:

(1) The language "primary range of flexion" means from -15° of hyperextension to +75° of flexion.

(2) The language "femoral component including at least one condylar element" to mean that in bi-condylar knees, both condyles must meet those requirements.

(3) The language "lying generally along a line extending laterally between the medial and lateral collateral ligament attachment points on the femur of the natural knee" is not indefinite.

It is so ordered.

DATED: November 28, 2005

/s/ Jose L. Linares
UNITED STATES DISTRICT JUDGE